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EXHIBIT 7

IACP COMMENTS to USP PROPOSED CHAPTER<797> PHARMACEUTICAL COMPOUNDING-STERILE PREPARATIONS
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Some of these comments incorporate the comments of McGuff Compounding Pharmacy, Dee Downing of Professional Compounding Centers of America and Analytical Research Laboratories also made significant contributions. IACP is thankful for their assistance.

Item #	Section in proposed chapter <797>	Current wording as proposed	Comments
1	RESPONSIBILITY OF COMPOUNDING PERSONNEL, ¶2 pg 500	All CSPs for administration by injection shall meet the purity and labeling requirements under Injections <1> and Particulate Matter in Injections <788>	Meeting the requirements of chapters 1 and 788 is impractical for extemporaneous pharmacy compounding. These chapters require adherence to chapters 71 and 85. There is no exception or exemption for single dose applications or for those medications that must be used immediately. Chapter 788 is well beyond the scope of pharmacy. The requirement should be limited to the labeling requirements under Injections <1>, which should be included in this chapter.
2	RESPONSIBILITY OF COMPOUNDING PERSONNEL, ¶2 pg 500	Dispenser shall ensure that CSPs maintain their correct strength within 10% of their labeled values	A requirement for testing to this end is overly onerous. A sampling testing program to ensure technique is sufficient. Individually testing every drug product to ensure labeled strength is inappropriate for pharmacy practice.
3	RESPONSIBILITY OF COMPOUNDING PERSONNEL, ¶3 pg 500	...safe limits and ranges for strength of ingredients....particulate matter	This requirement is not practical. Pharmacists often do not have this information. Safe limits and ranges for the strength of ingredients is determined by the physician. Establishing safe limits and ranges for particulate matter is not practical and should be deleted.
4	RESPONSIBILITY OF COMPOUNDING PERSONNEL, #3 pg 500	3. Opened, partially used ...tamper-evident conditions.	Tamper-evident conditions for partially used containers is beyond the scope of community pharmacy practice. Bulk drug substances are controlled by the pharmacist.
5	RESPONSIBILITY OF COMPOUNDING PERSONNEL, #4 pg 500	4. To minimize the generation of bacterial endotoxins water-containing preparations that are non-sterile during any phase of the compounding process are sterilized within 4 hours of the initiation of the compounding process.	This requirement is arbitrary (4 hours) and unduly restrictive. One can envision a compounding process that requires longer than 4 hours to complete and has little risk of allowing the bacterial growth.
6	RESPONSIBILITY OF COMPOUNDING PERSONNEL, #6 pg 500	6. Measuring, mixing and purifying devices are properly cleaned and validated to be accurate and effective.	Validating measuring and mixing devices is rarely necessary. In pharmacy practice we must trust that a graduated cylinder is capable of measuring accurately. It may be appropriate to verify effectiveness of an autoclave or to calibrate a scale. This factor must be revisited.
7	RESPONSIBILITY OF COMPOUNDING PERSONNEL, # 8 pg 500	8. Packaging is proven to be compatible and effective.	Proving that packaging is compatible and effective is beyond the scope of the practice of compounding. Pharmacists must ensure that they evaluate the packaging they chose, and we often must rely on their professional judgment.
8	RESPONSIBILITY OF COMPOUNDING PERSONNEL, #10 pg 500	10. Appropriate tests and inspections are performed	Should be reworded "Tests and inspections are performed when appropriate and practical prior . . ." This is consistent with ¶3 under RESPONSIBILITY OF THE COMPOUNDING PERSONNEL.

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9	RESPONSIBILITY OF COMPOUNDING PERSONNEL, #14 pg 501	14. Compounding procedures and manipulations are clearly separated from quality testing and inspection.	In community pharmacy practice this will often involve the same personnel. The meaning of this language is unclear.
10	CSP RISK LEVELS, ¶3 pg 502	In such cases, additional evidence must be obtained to ensure...	What additional evidence? Current text indicates that the pharmacist must perform stability testing to cover the beyond-use date. Stability testing is beyond the scope of pharmacy practice. Pharmacists can not obtain evidence for every drug in each set of individual conditions. Pharmacists must use professional judgment and use the beyond-use date guidance as discussed in great detail later in the chapter. This language must be deleted.
11	CSP RISK LEVELS, High-Risk Level ¶2 pg 504	All non-sterile measuring, mixing, and purifying devices...	This paragraph seems out of place. This paragraph is confusing and serves no purpose in its present location.
12	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, ¶1 pg 505	...standard nonpathogenic bacterial cultures may be added to nondispensible specimens of high-risk CSPs before terminal sterilization for subsequent evaluation by sterility testing.	Comments on this are provided later when this is described in more detail.
13	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, Sterilization Methods ¶1 pg 505	The selected sterilization process should achieve a 0.0001% probability, or no more than one chance in one million opportunities, that...	What does this mean for the practicing pharmacists? Pharmacists have no way of determining if a sterilization process is capable of this specific probability.
14	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, Sterilization Methods #1 pg 506	1. Colloidal fluid dispersions, emulsions, solutions, and suspensions that have been proven to remain...	The terminology "have been proven" suggests that the pharmacy must perform product stability testing before steam sterilization or as part of sterilization program. This type of stability testing is beyond the scope of pharmacy practice.
15	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, Sterilization Methods subsection, STERILIZATION BY FILTRATION ¶2 pg 506	The filter dimensions and material shall permit the sterilization process to be completed rapidly without replacement of the filter during the process.	Provided proper aseptic technique is employed, changing a filter during the process would not induce any greater risk than the initial set-up. Restricting the process to a single filter is not necessary or prudent. One can envision circumstances in which a pharmacist has a critical prescription and the filtration process requires a filter change.
16	VALIDATION OF COMPOUNDING ACCURACY AND	See comment	Indicating the use of "standard," non-pathogenic, bacterial cultures in a media fill is dangerous and may lead to cross contamination within the pharmacy. This recommendation should be removed from the chapter.

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	STERILIZATION, Sterilization Methods subsection, STERILIZATION BY FILTRATION ¶3&4 pg 506		I assume the writer is trying to guide the reader to perform a bacterial challenge/media fill test of the filter set-up. This is unnecessary provided that filter is tested for integrity by a suitable means before and after use. Commercial filters, for pharmaceutical purposes, should be tested by the manufacturer for integrity and a stated bubble point should be given. Following use, the filter should be subjected to the manufacturer's indicated integrity test (i.e. bubble point test) and shown to be integral after use. Any failure in the post-use bubble point test should be cause for rejection of the filtered compound.
17	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, Sterilization Methods subsection, STERILIZATION BY FILTRATION ¶4 pg 506	In both cases, the sterile filters are tested under conditions of duration, fluid flow rate, osmolarity, pH, pressure, process sequence, solvent composition, temperature, and viscosity that are similar to those of the CSP to be sterilized.	In the case where filter devices are assembled by compounding personnel, the device should be tested for integrity. Providing information on how manufactured filters are tested is irrelevant to this chapter.
18	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, Sterilization Methods subsection, STERILIZATION BY FILTRATION ¶5 pg 507	See comment	Is it recommended that the use of bacterial cultures occur every time? Again, the use of live bacterial cultures to be used in the pharmacy is not a sound practice. On addition, suggesting that one should use a swab from a human mouth or palm as an inoculum for the media used in a media fill is not a valid control parameter. If the intent of this procedure were to "challenge" the filter with live bacteria, it would be just as acceptable to run non-sterile media through the filter. Dehydrated commercial media prepared per the manufacturer's instructions will contain viable bacteria within the culture. In any case, conducting a bubble point test on the filter would indicate whether filter integrity was maintained during and after use.
19	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, Sterilization Methods subsection, STEAM STERILIZATION ¶1 pg 507	... aqueous preparations that have been proven to maintain their full chemical...	The terminology "have been proven" suggests that the pharmacy must perform product stability testing as part of sterilization program. Such testing is beyond the scope of pharmacy practice.
20	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION,	... by sterility testing of non-dispensable samples to which a standard nonpathogenic bacterial culture was added.	Need to clarify "non-dispensable." Is this intended to indicate the use of bacterial culture media?

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	Sterilization Methods subsection, STEAM STERILIZATION ¶3 pg 507		Proper validation challenge of steam sterilization process should be with bacterial spores shown to process a minimum resistance to the process. Such indicators could be prepared outside of the pharmacy and brought into the pharmacy sealed and ready for processing to eliminate cross-contamination hazards.
21	VALIDATION OF COMPOUNDING ACCURACY AND STERILIZATION, Sterilization Methods subsection, STEAM STERILIZATION ¶3 pg 507	See comment.	<p>Again, the use of live bacterial cultures to be used in the pharmacy is not a sound practice.</p> <p>On addition, suggesting that one should use a swab from a human mouth or palm as an inoculum for the media used in a media fill is not a valid control parameter. If the intent of this procedure were to "challenge" the filter with live bacteria, it would be just as acceptable to run non-sterile media through the filter. Dehydrated commercial media prepared per the manufacturer's instructions will contain viable bacteria within the culture.</p> <p>In any case, conducting a bubble point test on the filter would indicate whether filter integrity was maintained during and after use.</p>
22	ASEPTIC PROCESSING, ¶2 pg 508	Microorganisms in all medium-filled units showing visible evidence of microbial growth should be promptly identified...	Identifying microorganisms is beyond the scope of pharmacy. The only critical information is whether there are microorganisms present. This requirement needs to be deleted.
23	ACCESS CONTROL TO THE BUFFER ROOM AND ANTEROOM pg. 513		It is unclear whether it is required to have the isolated barrier within a buffer room.
24	ENVIRONMENTAL QUALITY AND CONTROL, Environmental Controls subsection, ¶4 pg 513	The air entering the buffer area should be fresh, HEPA-filtered, conditioned air.	The term "fresh" is potentially misleading and unnecessary. HVAC systems incorporating HEPA filters typically utilize a mixture of fresh and re-circulated air. Using 100% fresh air would require the area to be 100% exhausted to the outside. This requirement is not necessary and would increase cooling costs dramatically.
25	ACCESS CONTROL TO THE BUFFER ROOM AND ANTEROOM pg. 514	An anteroom as just described is necessary for high-risk operations	Many facilities today preparing low to high risk sterile products do not have a buffer room much less an anteroom. USP should determine the effect on businesses that this requirement would have. Pharmacies may very well be able to prepare sterile products without the necessity of an anteroom provided that validation, testing, and proper aseptic technique is used.
26	ENVIRONMENTAL QUALITY AND CONTROL, Suggested Standard Operating Procedures #12 pg 515	12. At the beginning of each shift and when spillage occurs, the SCE surface is wiped with a clean, non-linting wiper or sponge dampened with distilled water.	<p>As written, the item indicates that the entire surface of the SCE (including ceilings, walls, ceiling grids) must be wiped. Specifying distilled water is not as effective as specifying disinfectant/cleaner.</p> <p>The use of sponges in any clean room environment is not recommended. Sponges are notorious for harboring bacteria.</p>

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27	ENVIRONMENTAL QUALITY AND CONTROL, Suggested Standard Operating Procedures #13 pg 515	13. ...Before reuse, all internal surfaces are sanitized...	As written, the item indicates that the entire surface of the SCE (including ceilings, walls, ceiling grids) must be sanitized. This is not always necessary. Ceilings and walls of an SCE that is unoccupied, even with the HEPA-filter blowers turned off, will remain clean provided the room is unopened and personnel do not enter the room.
28	ENVIRONMENTAL QUALITY AND CONTROL, Environmental Control and Monitoring Program; Testing Program ¶5 pg 517	Subsequently, any significant change in the counts obtained, either a single spike or a gradual rise in the cfu count, would require investigation into the cause.	Quality control practices recognize that single spikes above an indicated alert level generally should not induce investigation. Such an occurrence is typically random and unpredictable. Investigating such occurrences is usually futile.
29	PROCESSING ¶1 pg 518	The evaluation process includes a written test of the fundamental knowledge of aseptic techniques and the preparation of sterile products, and performance...personnel are tested at six month intervals to determine continuing training needs, and...	Requiring written test especially every six months is unnecessary and overly restrictive. Having personnel conduct the media fill validation testing is far more relevant and telling.
30	PROCESSING, Components; NON-STERILE COMPONENTS ¶1 pg 519	...is opened, conditions under which the container can be opened, specific devices required to withdraw the contents to prevent contamination of the remaining contents, proper storage of the container, use within a reasonable period of time (6 or 12 months), and visual inspection upon removal and prior to use. The bulk drug substance may be repackaged into smaller and properly sealed containers (e.g. using shrink seal)...	Creating such a log for every substance and excipient is unreasonable and does not provide any added assurance. Rather, an inventory control system/procedure should be created that ensures such materials are stored properly, used on a FIFO bases, and have a Pharmacy determined expiration date based upon the pharmacist knowledge/expertise. Requiring all the other items listed in the current text is not appropriately placed in a log. Opened containers of bulk drug substances are not resealed using shrink seal or tamper evident seals in current pharmacy practice.
31	PROCESSING, Components sub section, NON-STERILE COMPONENTS ¶2 pg 520	Because finished CSPs are not usually tested for pyrogens, non-sterile bulk drug...	This entire paragraph seems to conflict with section "FINISHED PRODUCT RELEASE CHECKS AND TESTS, Pyrogen testing sub section" as stated on pg. 521 which requires pyrogen testing.
32	FINISHED PRODUCT RELEASE CHECKS AND TESTS, Sterility Testing ¶1 pg 521	The sterility test, including the sampling scheme, is conducted according to one of the USP methods (see sterility tests <71>)	Unique sterile extemporaneous preparations are often prepared by pharmacists on an individual patient basis. A unique formula may be used once for an individual patient. A unique formula may be used on a few patients. Often this may be a preservative-free injection used immediately following preparation. There must be some differentiation

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			<p>between this type of small volume compounding and larger volume sterile product preparation for groups of patients.</p> <p>Requiring adherence to sterility testing according to USP <71> for every high-risk CSP leads us to believe the committee is either not familiar with current pharmacy practice or is not familiar with the requirements of USP <71>. This guidance must be reconsidered and reworked. Among the problems:</p> <ol style="list-style-type: none"> 1. Bacteriostasis and fungistasis testing are inappropriate for preservative free preparations. This is generally beyond the scope of community pharmacy practice. 2. The sampling provisions are inappropriate, a minimum of 4 vials of the preparation must be tested. In many cases the prescription is for an individual patient and calls for less than 4 vials. <p>At most, this chapter should reference only the test procedures sections of USP <71> which include membrane filtration method and direct transfer method. In addition in-house sterility testing kits are available and appropriate when used in conjunction with a scheduled independent testing program.</p> <p>Pharmacy that complies with the other requirements of proposed chapter <797> represent little risk of actually preparing a non-sterile compound. The use of the sterility test is of such limited statistical significance as to be nearly worthless when applied to a properly controlled compounding operation. This is not to say that the sterility test should be eliminated, but rather to point out that the basis for the test is for detecting gross contamination of the final products and/or gross failure of the sterilization process. Not for applying a statistically valid basis for product release.</p> <p>Sterility testing should be exempted for very small batches given other requirements of the chapter are met. For larger batches a sampling protocol of 2% of the articles should be sufficient for testing.</p>
33	FINISHED PRODUCT RELEASE CHECKS AND TESTS, Pyrogen Test ¶1 pg 521	Each CSP prepared from non-sterile drug components or excipients, or from an intermediate compounded from a non-sterile component is tested for pyrogen or endotoxin according to the recommended methods (see Bacterial Endotoxins Test <85>).	<p>Unique sterile extemporaneous preparations are often prepared by pharmacists on an individual patient basis. A unique formula may be used once for an individual patient. A unique formula may be used on a few patients. Often this may be a preservative-free injection used immediately following preparation. There must be some differentiation between this type of small volume compounding and larger volume sterile product preparation for groups of patients.</p> <p>Requiring adherence to endotoxin testing according to USP <85> for every high-risk CSP leads us to believe the committee is either not familiar with current pharmacy practice or is not familiar with the requirements of USP <85>. This guidance must be reconsidered and reworked. Among the problems:</p>

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			<p>In some situations it may not be feasible to do perform an endotoxin study. In some situations it may not be feasible to obtain the results of the test before it must be administered to the patient. In addition it may only be feasible to use an in-house test which may provide appropriate assurance but may not comply with the extensive requirements of USP <85></p> <p>IACP would appreciate documentation that the committee has considered real-world scenarios in which sterile products are administered to patients and what types of end-product testing are appropriate given those scenarios. IACP would be willing to assist to the end.</p> <p>Endotoxin testing should be exempted for small batches of products given all other requirements in the Chapter are met. For larger batches, a sampling protocol of 2% of the articles should be set aside for testing.</p>
34	FINISHED PRODUCT RELEASE CHECKS AND TESTS, Potency Testing #4 pg 522	4. The final yield is confirmed to be consistent with the theoretical yield.	Final yield and theoretical yield need to be defined. It is assumed that the author intends the pharmacy to comply with GMP requirements regarding accounting for consumed materials through calculating the anticipated number of units that would be prepared based on the formula and batch size prepared. This is beyond the scope of pharmacy practice.
35	FINISHED PRODUCT RELEASE CHECKS AND TESTS, Potency Testing Last ¶ pg 522	Because beyond-use dating periods established from product...	This paragraph seems to be misplaced. Keep beyond-use dating requirements in their appropriate section.
36	STORAGE AND BEYOND-USE DATING. ¶2 pg 522	Thus, as an adjunct sterility assurance measure, CSPs not intended for prompt use should be stored at a temperature no higher than 4°C, that is, at a temperature expected to inhibit microbial growth.	As written, the sentence is too restrictive and must be revised. Not all drug products are stable at this temperature. Storage temperature should be determined by the pharmacist based on the chemical characteristics of the specific drug product.
37	STORAGE AND BEYOND-USE DATING, ¶2 pg 522	Mult-day CSPs should be started promptly after preparation and administration should be completed within 7 days.	There are numerous situations where a 7-day limit is too restrictive for infusion therapy.
38	BEYOND-USE DATING. ¶3	A written procedure has to be in place that details what is to be done when this situation occurs... the actual stability of the product has to be determined...	<p>This requirement is unnecessary and is overly restrictive for pharmacy practice. The pharmacist should ensure the drug product is stored appropriately for the labeled beyond-use date. Storage in non-optimal conditions requires an evaluation of the drug product and beyond-use date by the pharmacists.</p> <p>The implied requirement for stability studies is beyond the scope of pharmacy.</p>

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39	BEYOND-USE DATING Determining Beyond Use Dates pg 524	If possible, pharmacists should obtain a letter from the manufacturer certifying the beyond-use dating period in cases where it differs from that in the package insert.	This is not possible. Manufacturers will not provide this information and it is counterproductive to allocate a pharmacist's time to attempting to gain this information.
40	BEYOND-USE DATING, Determining Beyond Use Dates ¶2 pg 524	Beyond-use dating not specifically referenced in the package insert should not exceed 30 days.	As written, the sentence is too restrictive. The intent of this section is to provide guidance and recommendations to the pharmacists regarding establishing beyond-use dating. Prescriptions for alternative concentrations or variant formulations of drugs with comparative commercial counterparts (congeners) can be reasonably assumed to remain stable for as long as the commercial product. Therefore, the pharmacist may chose to extend the beyond-use date to a time frame that is reasonable in order to allow the pharmacy to comply with the testing requirements in the chapter (e.g. sterility and endotoxin testing) while still maintaining a useful dating period for the product to cover an anticipated use period. If a limit must be imposed, then this limit should be 180 days. A 180 day time frame would be sufficient to cover all circumstances the pharmacy may encounter.
41	STORAGE AND BEYOND-USE DATING, Determining Beyond-Use Dates ¶3 pg 524	Beyond-use dates should be conservatively assigned, and where such dating is not established by the product-specific instrumental analysis, limited to 30 days.	See comment above.
42	STORAGE AND BEYOND-USE DATING, Determining Beyond-Use Dates ¶3 pg 525	Pharmacists should subsequently obtain a record of the specific basis used to establish the beyond-use date for each CSP that deviates from the approved package insert.	This requirement is unnecessary and generates unneeded paperwork. It is not done in current pharmacy practice.
43	NONINSTITUTIONAL COMPOUNDING PHARMACIES (NICPs) pg 529		There is extensive information on the role of NICPs to dispense sterile drug products in the home use setting. However, there is no information on dispensing sterile drug products to physician's offices for physician administration. References to patient home should be expanded to include physician's office or a separate section should be added to provide guidance to the physician and staff in the storage and administration of sterile drug products.
44	PACKING TRANSIT PACKING TRANSIT pg 530-532		These sections need to be reassessed in their entirety as they are greatly flawed. There are two sections for each "transit" and "packing" for no apparent reason. Albeit great guidelines, these newly deemed 'requirements' are well beyond the scope of pharmacy practice.
45	MAINTAINING	The NICP should have written	The requirement should be that the pharmacist should ensure that proper packaging is used.

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	PRODUCT QUALITY AND CONTROL AFTER THE CSP LEAVES THE PHARMACY, Sterile Preparations For Institutional Use; Packing ¶3, pg 530	procedures that specify packing techniques, configurations, and materials for groups of products with common storage	Requiring written procedures for packaging for each class of drugs is beyond the scope of pharmacy.
46	PACKING ¶4 pg 530	The patient should have written procedures that specify the expected packing techniques, configurations and materials for the products obtained from an NICP. The procedures should...	The purpose of this must be explained. It is unnecessary and beyond the scope of this chapter and beyond the scope of pharmacy practice. Do manufactures comply with this at the patient level? Why would this apply to pharmacy prepared products?
47	PACKING ¶5 pg 530	The NICP should ensure that transit specifications and procedures are effective.	The example cited here to comply with this standard is beyond the scope of pharmacy practice.
48	TRANSIT ¶2 pg 531	The carrier should be provided with a written statement of shipping requirements and the carrier should provide written assurance of capability and commitment to fulfilling these requirements before the carrier's services are engaged.	This is beyond the capabilities of the pharmacist. In manufacturing where significant income for the carrier is at stake, the carrier may be willing to provide such written assurance. It is doubtful that they will provide it for a small community pharmacy. Such documentation is beyond the scope of pharmacy practice.
49	TRANSIT ¶4 pg 531	Both the NICP and the receiving pharmacy in the health care facility should have effective systems for the routine evaluation of shipping performance.	This may be feasible for health system pharmacy but it is beyond the scope of community pharmacy practice.
50	IN THE HOME pg 532		This section should take into account the sterile drug products that are stored in the physician's office as well.
51	IN THE HOME #3 pg 532		Ensuring the patient has a temperature measurement device is often not appropriate especially for short-term use.

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52	OUTCOME MONITORING pg 533	The pharmacy is responsible for developing a patient monitoring plan, which includes written outcome measures and systems for routine patient assessment. The outcome monitoring system should provide information suitable for the evaluation of the quality of patient care...examples of assessment parameters include infection rates, rehospitalization rates, incidence of ADRs, catheter complications, and other variables...	This may be appropriate for home health care or health system pharmacy, but it is not applicable to community pharmacy practice.